Remarks/Arguments:

The above Amendments and these Remarks are in reply to the Office Action mailed May 27, 2005. No fee is due for the addition of any new claims.

Claims 1-6, 9-16, 18-19, 21, 23, 26-43 were pending in the Application prior to the outstanding Office Action. In the latest Office Action dated May 27, 2005 the Examiner rejected claims 1-6, 9-16, 18-19, 21 and 23-40.

Because of the discrepancy between the pending claims and the Examiner's rejection, the Applicant makes the following notations: The Applicant had previously (March 30, 2005) attempted to withdraw Claims 24 and 25 and add Claims 41-43. In an advisory action dated April 25, 2005 the Examiner indicated that the March 30, 2005 proposed amendments would not be entered. Thereafter, an RCE was filed June 23, 2005. In the RCE, the Applicants requested that the March 30, 2005 amendments be entered.

In the present Response the Applicant reiterates the withdrawal of Claims 24 and 25, and the addition of Claims 41-43. Further, in the present Response the Applicant currently amends Claims 1, 21, 26, 39 and 40, leaving for the Examiner's present consideration claims 1-6, 9-16, 18-19, 21, 23, 26-43. Reconsideration of the rejection is requested.

Claim 23

The Examiner believed that claim 23 was incorrectly drafted. Claim 23 is supported in the specifications at least by Figure 1G which shows the "concave sockets is orientated to lie parallel to a sagittal plane of a patient" and by Figure 1E which shows the "concave socket is

orientated to lie in a plane perpendicular to a sagittal plane of a patient". Thus both embodiments of the claimed subject matter are shown in the Figures.

Ferree Reference

The Examiner considered the declaration by the inventor to be ineffective to overcome the Ferree reference, US Patent Application Publication No. US 2004/0106998 (hereinafter Ferree).

The Ferree discloses "... a cruciate shaped axle ... much like a universal joint" [0007], where "[t]he top and bottom components 104, 104' rotate around the four arms of the axle" [0025]. In all of the different embodiments (shown by the Figures), the Ferree upper plate is recessed into the lower plate. In contrast, the Applicant's third part is not a universal joint but rather "... is in the form of a crossbar ..." [0023], where the "first piece having a first socket" and "a second piece having a second socket and a crossbar member that is at least partially received in the first socket and the second socket ...". The method by which the Ferree device enables flexion extension and lateral bending is thus different.

Further, the Applicant herein supplies a declaration by Steve Mitchell. In the declaration, Mr. Steve Mitchell states that he is an employee of St Francis Medical Technologies and specializes in spinal implant developments. (Mitchell declaration, ¶3). Mr. Mitchell, is the sole inventor of U.S. patent application 10/684,668. (Mitchell declaration, ¶4). Further, in the declaration, Mr. Mitchell declares under penalty of perjury that he showed a prototype embodiment of the invention in May, 2002 to an internal research and development team. (Mitchell declaration, ¶6). As such, the inventor is able to establish actual reduction to practice of

this invention prior to the effective date of the Ferree reference. Therefore, the Applicant respectfully requests that the Examiner reconsider this rejection.

Rejection under 35 USC 102(e)

The Applicant has amended Claim 1 with the limitation that "after an implant is inserted and the patient has healed at least the first piece remains capable of pivoting about the crossbar member to accommodate at least one of flexion, extension and lateral bending". The Examiner cites Wagner et al. (6,706,070) (hereinafter Wagner) as anticipating the Applicant's invention. However, Wagner's invention is to fix adjacent vertebrae so that they can become fused or immobile after the operation. Firstly, in the 'Field of Invention', Wagner indicates the invention "relates to methods and apparatus for promoting an intervertebral fusion, and more particularly to an apparatus for insertion into a space between adjacent vertebrae to facilitate an intervertebral fusion while maintaining a substantially natural lordosis of the human spine" (column 1, lines 12-17). Secondly, in the 'Summary of the Invention', Wagner notes that "... the invention relates to a fusion device for facilitating an interbody fusion between neighboring vertebrae ..." (column 2, lines 19-21). Thirdly, once the surgeon implanting the alignment/fusion device sets the screws, the implant is rigid allowing fusion of adjacent vertebrae, no "flexion, extension or lateral bending" is possible.

The Current amendment makes clear that "after an implant is inserted and the patient has healed at least the first piece remains capable of pivoting about the crossbar member to accommodate at least one of flexion, extension and lateral bending". As such Claim 1 can be distinguished from the prior art since the Wagner does not disclose a device that remains capable of pivoting after the implant is inserted and the wound has healed. The amendment to Claim 1 is

supported in the specification at least at the ninth and tenth sentences of paragraph [0037] and the last sentence of paragraph [0040].

Claims 39 and 40 have also been amended to include the limitation that the device "allows movement after an implant is inserted and the patient has healed retention of bending". As such, the Applicant believes that Claims 39 and 40 are not disclosed in Wagner.

Specification

The specification has been amended to refer to first piece, first spacer member, first socket, first bar, second piece, second spacer member, second socket, second bar, upper implant and lower implant. The terms first piece, first spacer member, first socket, first bar, second piece, second spacer member, second socket, second bar, upper implant and lower implant were all present in the original claims as filed and thus no new matter has been imported into the specifications.

Rejection based on 35USC §112, First Paragraph

The Examiner rejects Claims 1 and 21 on the basis that the limitation is broader than the specification. In paragraph [0023], the specification sets out that the device "facilitates pivotal or rotational and also twisting movement of the first plate ***110*** and the second plate ***120***, relative to each other". The structure comprises "a first piece having a first socket" and "a second piece having a second socket and a crossbar member that is at least partially received in the first socket and the second socket ...". This structure by enabling the crossbar to be located in each concave socket or not inherently facilitates flexion, extension and lateral bending. Thus the specification

supports "flexion, extension and lateral bending" of a person fitted with such a device. Thus the limitation of Claim 1 is supported by the specification at least at paragraph [0023].

Similarly for Claim 21, the structure comprises "an upper implant further comprising, a first surface ... and a second surface having a first concave socket" and "a lower implant further comprising, a first surface ... and a second surface having a second concave socket" and "a crossbar member with a first beam that is received in the first concave socket of the upper implant and a second beam that is received in the second concave socket of the lower implant". Such a structure by enabling the crossbar to be located in each concave socket or not, inherently facilitates pivoting. Thus the specification supports "at least one of the upper and lower implant is capable of pivoting about the crossbar" of a person fitted with such a device. Thus the limitation of Claim 21 is supported by the specification at least at paragraph [0023].

Rejection based on 35USC §112, Second Paragraph

The Examiner rejects Claim 23 as being indefinite. The Applicant has identified in the specification the basis for the claim (see above, page 8, last paragraph). The Applicant respectfully requests that the Examiner reconsider the rejection.

Rejection based on 35USC §102(b)

The Examiner rejects Claims 1-6, 9-14 and 19 under 35 USC 102(b) as being anticipated by Yarrow, US Patent No. 4,499,613 (hereinafter Yarrow). The Examiner states that Yarrow teaches an implant comprising a first piece having a first socket, a second piece having a second socket and a crossbar member that is at least partially received in the first socket and the second socket.

Yarrow in 'Background of the Invention' states that "The parts are interconnected by a bolt ..." (column 1, lines 22-23). In the 'Summary of the Invention' discloses the ".... bolt extending through the foot and cup members to retain the components in assembled fashion" (column 2, lines 1-2), which "... cup shaped member may be secured to the bottom surface of the leg member 12 by suitable fastening members ..." (column 3, line 11-13). Yarrow goes on to indicate that "An elongated threaded bolt 52 interconnects the leg member 12 and foot member 16 ..." (column 3, line 47-48) and "The nut 60 adjustably engages the upper surface of the cup shaped member 38 ..." (column 3, line 55-58) "so that the nut can be adjustably tightened to retain the members in assembled relation ..." (column 3, line 61-63). Thus Yarrow discloses a crossbar member that slots into and thereby is attached to the second piece. As such the crossbar in Yarrow is not capable of pivoting about the crossbar member to "accommodate flexion, extension and lateral bending". Thus, Yarrow does not disclose this element of the claim. Since claims 2-6, 9-16 and 18-19 properly dependent on this limitation of Claim 1, Yarrow does not disclose this element of these claims.

With regard to Claim 19, the Examiner points out that Yarrow discloses a foot attached to the second piece and the Examiner notes that a foot is sometimes referred to as a keel. However, as stated above the crossbar in Yarrow is not able to "accommodate flexion, extension and lateral bending". As such Yarrow does not disclose each and every element of claim 19.

Rejection based on 35USC §102(e)

The Examiner rejects Claims 1, 4-6, 9-12, 14, 21-23 and 35-40 under 35 USC 102(e) as being anticipated by Ferree. The Applicant requests that the Examiner reconsider this ground of rejection. Ferree characterizes their device as a universal joint, whereas the Applicant's crossbar

is fixed as discussed above (page 9, second paragraph). Further, based on the Applicant's declaration, the Applicant demonstrates actual reduction to practice before Ferree's earliest filing date of October 4, 2002 (see page 9, third paragraph).

Claims 1-6, 9-16 and 18-19

The Examiner rejects Claims 1-6, 9-23 and 26-40 under 35 USC 102(e) as being anticipated by Wagner.

Claim 1 has been amended to include the limitation "after an implant is inserted and the patient has healed at least the first piece remains capable of pivoting" to distinguish the Applicant's device from the invention of Wagner which is directed towards fusing the vertebrae together. Since claims 2-6, 9-16 and 18-19 properly dependent on this limitation of claim 1, Wagner does not disclose this element of these claims.

Claims 21, 23, 37-38

Claims 21 has been amended to include the limitation "after an implant is inserted and the patient has healed at least one of the upper and lower implant remains" to distinguish the Applicant's device from the invention of Wagner which is directed towards fusing the vertebrae together. Since claims 23 and 37-38 properly dependent on this limitation of claim 21, Wagner does not disclose this element of these claims.

Claims 26-34

Claim 26 has been amended to include the limitation "remains able to accommodate at least one of flexion, extension and lateral bending after an implant is inserted and the patient has

healed" to distinguish the Applicant's device from the invention of Wagner which is directed towards fusing the vertebrae together. Since claims 27-34 depend on claim 26, Wagner does not disclose this element of these claims.

Claims 35 and 36

Claims 35 and 36 include the limitation "continuous selective movement of the vertebral bodies" to distinguish the Applicant's device from the invention of Wagner which is directed towards fusing the vertebrae together. The Examiner directs the Applicant to the embodiment shown in Figures 8-9. In this embodiment, the "[b]one graft material is preferably inserted thorough the anterior end and packed between the engaging plates" (column 13, lines 60-63) will fuse the adjacent vertebrae and therefore "continuous selective movement of the vertebral bodies" will not be possible. Thus Wagner does not disclose this element of claims 35 and 36.

The Examiner also directs the Applicant to the embodiment shown in Figures 42-49. In this "alternative embodiment of an interbody fusion device" (column 27, line 1), the bracket assembly 706 (898 in Figure 45) fixes the separation between the first piece 702 (900 Figure 46) and the second piece 704 (904 Figure 46) and otherwise limits the range of movement of the crossbar 750 (858, 878 in Figure 45). Screws 850, 860, 870, and 880 may still further include indentations (e.g., indentations 858 and 878, visible in FIG. 45). The indentations may be configured to receive the tip of an adjusting screwdriver" (column 30, lines 7-10). Once the surgeon has set the device, and the device has fused no "continuous selective movement of the vertebral bodies" is allowed. As such, Wagner does not disclose each and every element of claims 35 and 36.

Claims 39 and 40

Claims 39 and 40 have also been amended to include the limitation that the device " after an implant is inserted and the patient has healed" to distinguish the Applicant's device from the invention of Wagner which is directed towards fusing the vertebrae together. As such Wagner does not disclose each and every element of Claims 39 and 40.

The Examiner directs the Applicant to consider all configurations taught by Wagner. The Applicant respectfully submits that the Examiner has not met his burden to "... provide an explanation and rationale in the Office action as to why the prior art element is an equivalent". MPEP 2183. The Applicant respectfully requests clarification of what configurations taught by Wagner either "allows movement after an implant is inserted and the patient has healed" or "continuous selective movement of the vertebral bodies".

Rejection based on 35USC §103

The Examiner rejects Claims 15-20 under 35 USC 103(a) as being patentable over Ferree in view of Marnay, PCT Application No. WO 01/01893 (hereinafter Marnay). As discussed above, the Applicant has shown that Ferree is neither anticipatory nor prior art to the Applicants invention and as such is not available to be combined with Marnay. The Applicant requests that the Examiner reconsider this rejection.

The references cited by the Examiner but not relied upon have been reviewed, but are not believed to render the claims unpatentable, either singly or in combination.

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: 9/26/05

By: _____
Sheldon R. Meyer
Reg. No. 27,660

FLIESLER MEYER LLP
Four Embarcadero Center, Fourth Floor
San Francisco, California 94111-4156
Telephone: (415) 362-3800
Customer No. 23910